



04-05-07

PATENT *HPW*

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Jeffrey S. Bland, et al.
Serial No.: 10/735,526
Filing Date: December 11, 2003
Title: Medical Compositions for Balancing Bodily Processes
Confirmation No.: 3771
Art Unit: 1656
Docket No.: 062114-0077

CERTIFICATE OF MAILING OR TRANSMISSION

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Date: April 4, 2007

Jacqueline Andreu
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M.S. Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER

Enclosed for filing in connection with the above-referenced patent application are the following documents:

- 1) Information Disclosure Statement (2 pages);
- 2) Information Disclosure Statement by Applicant (Form 1449) (5 pages);
- 3) References cited in IDS by Applicant (C1-C40); and
- 4) Return Receipt Postcard.

The commissioner is hereby authorized to charge \$180.00 and any additional fees that may be required, or credit any overpayment, to our Deposit Account No. 50-1133.

Respectfully submitted,

Date: April 4, 2007

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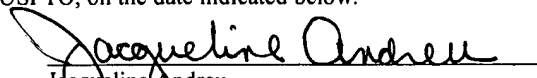
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Sir:

INFORMATION DISCLOSURE STATEMENT

Applicants and their attorney are aware of the following publications and information, listed on the attached Form PTO-1449 Form, and in accordance with 37 CFR §1.97(b) hereby submit these publications for the Examiner's consideration. According to the United States Patent and Trademark Office OG Notices: 05 August 2003, copies of cited U.S. patents and U.S. patent application publications are waived and not submitted with this Statement. Enclosed are copies of other references cited as C1-C40. This Statement is being filed before the receipt of a Final Office Action from the Patent and Trademark Office.

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, the Applicant understands that the Examiner will make an independent evaluation of the cited publications.

04/06/2007 RMEBRAHT 00000013 501133 10735526

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Dated: April 4, 2007

A handwritten signature in black ink, appearing to read "Atabak Royae", is written over a horizontal line.

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BST99 1536839-1.068911.0077

Subst. for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Application Number	10/735,526
				Filing Date	12/11/03
				First Named Inventor	Jeffrey S. Bland
				Art Unit	1656
				Examiner Name	Suzanne Marie Noakes
Sheet	1	of	5	Docket Number	062114-0077
U.S. PATENT DOCUMENTS					
Examiner Initials ¹	Cite No. ¹	Document Number Number-Kind Code ²	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	A1	US 5,330,972 A	07-1994	Cope, Frederick O.	
	A2	US 5,292,538	03-08-1994	Paul, et al.	
	A3	US 5,569,459 A	10-29-1996	Shlyankevich, Mark	
	A4	US 5,679,806 A	10-21-1997	Zheng, et al.	
	A5	US 5,830,887 A	11-1998	Kelly, Graham Edmund	
	A6	US 5,837,256 A	11-17-1998	Clark, et al.	
	A7	US 6,150,399	11-21-2000	Patel, et al.	
	A8	US 6,261,565 B1	07-17-2001	Empie, et al.	
	A9	US 2001/0001307 A1	05-17-2001	Ueda, et al.	
	A10	US 2001/0039296 A1	11-2001	Bagchi et al.	
	A11	US 2002/0025360 A1	02-28-2002	Yang, et al.	
Examiner Signature				Date Considered	

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Sheet	2	of	5	Docket Number	062114-0077
OTHER					
Examiner Initials ¹	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published			T ²
	C1	Andersson, et al., "Plasma Homocysteine Before and After Methionine Loading With Regard to Age, Gender, and Menopausal Status," European J. of Clinical Invest. (1992) Vol. 22, pp. 79-87.			
	C2	D. A. Bender, "Novel Functions of Vitamin B ₆ ," Proc. Nutr. Soc. Vol. 53, pp. 625-630 (1994).			
	C3	A. Bendich, "The Potential for Dietary Supplements to Reduce Premenstrual Syndrome (PMS) Symptoms," J. Amer. Coll. Nutr. Vol. 19, No. 1, 3-12 (2000).			
	C4	Berman, et al., "Vitamin B-6 in Premenstrual Syndrome," 90 Am J. Diet. Assoc. 859-861 (1990).			
	C5	J.S. Bland, "Nutritional Approaches to Steroid Hormone Balance," New Approaches to Anti-Aging: Nutritional Neuroendocrinology, 2001 Seminar Syllabus, The Institute of Functional Medicine, Inc., pp. 113-135.			
	C6	J.S. Bland, "Functional Role of Estrogen Metabolism," Improving Intercellular Communication in Managing Chronic Illness: A Functional Medicine Approach to Regulating Biochemical Mediators," 1999 Seminar Series Syllabus, HealthComm International, Inc., pp. 86-107.			
	C7	J.S. Bland, "Nutritional Influences on Available Hormone" Improving Intercellular Communication in Managing Chronic Illness: A Functional Medicine Approach to Regulating Biochemical Mediators," 1999 Seminar Series Syllabus, HealthComm International, Inc., pp. 114-124.			
	C8	J.S. Bland, "Methyltetrahydrofolate Reductase (MTHFR) Polymorphism, Homocysteine, and 5-methyleterahydrofolate (5-MeTHF)," Improving Intercellular Communication in Managing Chronic Illness: A Functional Medicine Approach to Regulating Biochemical Mediators," 1999 Seminar Series Syllabus, HealthComm International, Inc., pp. 174-184.			
	C9	Butterworth, et al., "17 β -Estradiol Metabolism by Hamster Hepatic Microsomes Implications for the Catechol-O-methyl Transferase-Mediated Detoxication of Catechol Estrogens," Drug Metab. Dispos, Vol. 24, No. 5, 588-594 (1996).			
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				Examiner Name	Suzanne Marie Noakes
Sheet	3	of	5	Docket Number	062114-0077
OTHER					
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published			T ²
	C10	A. Cassidy, "Potential Tissue Selectivity of Dietary Phytoestrogens and Estrogens," Current Opin. Lipdol. 47-52, Fol. 10(1) Feb. 1999.			
	C11	C.J.M. Arts, "Effects of Dietary Fibre on Breast Cancer Pathogenesis," Proc. of 5 th Symp. on Analysis of Steroids, Szombathely, Hungary, 1993 (S. Görög, ed).			
	C12	Susan R. Davis, et al., "Phytoestrogens in Health and Disease," Recent Progress in Hormone Research, Vol. 54, pp. 185-211 (1999).			
	C13	De Souza, et al., "A Synergistic Effect of a Daily Supplement for 1 Month of 200 mg Magnesium Plus 50 mg Vitamin B ₆ for the Relief of Anxiety-Related Premenstrual Symptoms: A Randomized, -Double Blind, Crossover Study," J. Women's Health & Gender-Based Medicine, Vol. 9, # 2, 2000, pp. 131-139.			
	C14	Garner, et al., "Catechol Metabolites of Polychlorinated Biphenyls Inhibit the Catechol-O Methyltransferase-Mediated Metabolism of Catechol Estrogens," Toxicol. Appl. Pharmacol., Vol. 162, 115-123, 2000.			
	C15	H. Gerster, "The Potential Role of Lycopene for Human Health," J. Amer Coll Nutr. No. 16, No. 2, 109-126 (1997).			
	C16	Goodman, et al., "COMT Genotype, Micronutrients in the Folate Metabolic Pathway and Breast Cancer Risk," Carcinogenesis, Vol. 22, No. 10, pp. 1661-1665, 2001.			
	C17	D.C. Hall, "Nutritional Influences on Estrogen Metabolism," Applied Nutritional Science Reports, Advanced Nutritional Publications, Inc., 2001, pp. 1-8.			
	C18	Hansen, et al., "Changes in Vitamin B-6 Status Indicators of Women Fed a Constant Protein Diet with Varying Levels of Vitamin B-6," Am J Clin Nutr, 1997; 66: 1379-87.			
	C19	Kaufman, et al., "A Comparative Survey of Leguminous Plants as Sources of the Isoflavones, Genistein and Daidzein: Implications for Human Nutrition and Health," J. Altern. Complement Med, Vol. 3, #1, 1997, pp. 7-12.			
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Sheet	4	of	5	Docket Number	062114-0077
OTHER					
	C20	Kuiper, et al., "Interaction of Estrogenic Chemicals and Phytoestrogens with Estrogen Receptor β 3," Endocrinology, Vol. 139, No. 10, 1998, pp. 4252-4263.			
	C21	LEF Cancer Protocols: Suggested Foods and Supplements, http://www.cancertutor.com/Other/Mirror_Lymphoma.html , pages 1-22.			
	C22	G. Levy, "Sulfate Conjugation in Drug Metabolism: Role of Inorganic Sulfate," Federation Proc, Vol. 45, No. 8, July 1986, pp. 2235-2240.			
	C23	Liska, et al., "Detoxification: A Clinical Monograph," Institute for Functional Medicine, Inc., 1999, pp.1-41.			
	C24	London, et al., "Efficacy of Alpha-Tocopherol in the Treatment of the Premenstrual Syndrome," 32 J. Reprod. Med, 400-404 (1987).			
	C25	Lukaczer, et al., "Clinical Effects of a Proprietary Nutritional Supplement in Postmenopausal Women: a Pilot Trial," Functional Medicine Research Center, Research Report No. 113, December 2002.			
	C26	Lukaczer, et al., "Effect of a Proprietary Nutritional Supplement on Weight and Blood Pressure in Postmenopausal Women," Addendum to Research Report #113, December 2002.			
	C27	Lukaczer, et al., "Improvement in Symptoms and Estrogen Metabolism in Women with Premenstrual Syndrome (PMS) Using New Formulated Medical Food," Research Report #110, May 10, 2001, Functional Medicine Research Center.			
	C28	Martin, et al., "Interactions Between Phytoestrogens and Human Sex Steroid Binding Protein," Life Sciences, Vol. 58, No. 5, pp. 429-436, 1996.			
	C29	Mazur, et al., 1988, Isoflavonoids and Lignans in Legumes: Nutritional and Health Aspects in Humans, Nutritional Biochemistry, Volume 9, pages 193-200.			
	C30	Sherwood, et al., "Magnesium and the Premenstrual Syndrome", 23 Ann Clin Biochem 1986: 23: 667-670.			
	C31	Shultz, et al., "In Vitro Binding of Steroid Hormones by Natural and Purified Fibers," Nutr Cancer 8, 141-147, 1986.			
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	C32	Stahl, et al., "Perspectives in Biochemistry and Biophysics," Archives of Biochemistry and Biophysics, Vol. 336, No. 1, Dec. 1, pp. 1-9, 1996.			
	C33	Susan, et al., "Induction of Glutathione S-Transferase Activity by Curcumin in Mice", 42 Drug Res. No. 7 962-964 (1992).			
	C34	Tamimi, R.M. et al. Prospects for Chemoprevention of Cancer, 2002, Journal of Internal Medicine, Volume 251, pages 286-300.			
	C35	Tully, et al., "Modulation of Steroid Receptor-Mediated Gene Expression by Vitamin B ₆ ," The FASEB Journal, Vol. 8, March 1994, pp. 343-349.			
	C36	Verma, et al., "Curcumin and Genistein, Plant Natural Products, Show Synergistic Inhibitory Effects on the Growth of Human Breast Cancer MCF-7 Cells Induced by Estrogenic Pesticides," 233 Biochem Biophys. Res. Comm., 692-696 (1997).			
	C37	Verma, et al., "The Inhibition of the Estrogenic Effects of Pesticides and Environmental Chemicals by Curcumin and Isoflavonoids," Environmental Health Perspective, Vol. 106, #12, Dec. 1998.			
	C38	Wyatt, et al., "Efficacy of Vitamin B-6 in the Treatment of Premenstrual Syndrome: Systematic Review," BMJ, Vol. 318, 22 May 1999, pp. 1375-1381.			
	C39	Yim, et al., "Use of N-Acetyl Cysteine to Increase Intracellular Glutathione During the Induction of Antitumor Responses by IL-2," J. Immunol, 1994, 152: 5796-5805.			
	C40	Zhu, et al., "Methyl-deficient Diets, Methylated ER Genes and Breast Cancer: An Hypothesized Association," Cancer Causes and Control, 1998, 9, pp. 615-620.			
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